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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/633,871

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Ronald F. Renzi

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11/17/2006

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EXAMINER

HYUN, PAUL SANG HWA

ART UNIT

PAPER NUMBER

1743

DATE MAILED: 11/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/633,871

Applicant(s)

RENZI ET AL.

Examiner

Paul S. Hyun

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 7, 9-21, 57 and 58 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 7, 9-21, 57 and 58 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 March 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/21/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

REMARKS

Claims 1-4, 7, 9-21, 57 and 58 are pending. In response to a restriction requirement imposed on June 13, 2006, Applicants elected the prosecution of claims 1-4, 7, 9-21, 57 and 58. Applicants cancelled claims 22-30, 32-56, 59 and 60 without prejudice.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the power module and the reservoirs comprising multiple chambers must be shown or the features must be canceled from the claims. No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New

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Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The limitation "low-dispersion channel" recited in the claim is indefinite. It is not clear if the limitation is referring to a separate channel distinguishable from the separation channel, or if the limitation is referring to a characteristic of the separation channel.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

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2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims **1-4, 7, 9, 10-16, 18-21, 57 and 58** are rejected under 35 U.S.C. 103(a) as being unpatentable over Coville et al. (US 6,398,956 B1) in view of Coville et al. (US 4,695,430).

US 6,398,956 B1 discloses a microfiltration apparatus (see Fig. 3A). The apparatus comprises a base 14, a needle 16, and a sealed reservoir 26 adapted to be pierced by the needle. The base 14 is sealed to a microfluidic chip 20. The microfluidic chip comprises an inlet 11, a separation channel 24 in communication with inlet 11, a sample introduction port 15 in communication with inlet 11, and a filter 18. The apparatus disclosed by US 6,398,956 B1 differs from the claimed invention in that the reference does not explicitly disclose a detection module, an interface, or a power module. However, the reference does disclose that it is well-known to couple a microfiltration device to an automated apparatus for analyzing the filtrate for various biological aspects, such as blood clotting time (see lines 18-23, col. 1).

US 4,695,430 discloses an apparatus for analyzing biological fluids contained in a single housing. The apparatus is adapted to be used with a microfiltration device (see line 61, col. 6). The apparatus comprises an optical detector for analyzing the filtered sample (see Abstract), an interface in the form of display 14 for displaying the results of the analysis, and a power source (see line 22, col. 19).

It would have been obvious to one of ordinary skill in the art to couple the microfiltration apparatus disclosed by US 6,398,956 B1 to the analyzer disclosed by US

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4,695,430 so that the sample filtered by the microfiltration apparatus disclosed in US 6,398,956 B1 can be analyzed by the analyzer disclosed in US 4,695,430.

US 4,695,430 also discloses that devices analogous to the one disclosed by the reference comprises an automated clotting time measurement means. The means comprises the use of a "fibrin switch" in which the physical formation of fibrin strands in a reaction mixture serves to complete an electrical circuit between two electrodes, thus stopping a timer (see lines 50-63, col. 1). It would have been obvious to one of ordinary skill in the art to provide the modified apparatus with a fibrin switch means comprising electrodes in a separate chamber of the sample container to provide the modified apparatus with a means for detecting clotting time of blood samples.

Although neither US 6,398,956 B1 nor US 4,695,430 disclose a plurality of reservoirs and microfluidic chips and detectors for processing the plurality of reservoirs, it would have been obvious to one of ordinary skill in the art to provide a plurality of reservoirs and corresponding microfluidic chips and detectors to the modified apparatus so that it can process a plurality of samples simultaneously. See *In re Harza*, 274 F.2d 669, 124 USPQ 378 (CCPA 1960) (holding that mere duplication of parts has no patentable significance unless a new and unexpected result is produced).

Although the modified apparatus would not be portable or hand-held, the fact that a claimed device is portable or movable is not sufficient by itself to patentably distinguish over an otherwise old device unless there are new or unexpected results. See *In re Lindberg*, 194 F.2d 732, 93 USPQ 23 (CCPA 1952).

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Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Coville et al. in view of Coville et al. as applied to claims 1-4, 7, 9, 10-16, 18-21, 57 and 58, and further in view of Strandberg, Jr. et al. (US 5,043,590).

Neither Coville et al. references disclose a laser diode. However, US 4,695,430 discloses that the optical detector can comprise an LED.

Strandberg, Jr. et al. disclose that a laser diode is superior to an LED because a laser diode has a lifetime of greater than 10 years and has the ability to focus beam to micro-size spots (see lines 55-65, col. 5).

In light of the disclosure of Strandberg, Jr. et al., it would have been obvious to one of ordinary skill in the art to substitute the LED disclosed by US 4,695,430 with a laser diode because a laser diode has a lifetime of greater than 10 years and has the ability to focus beam to micro-size spots.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul S. Hyun whose telephone number is (571)-272-8559. The examiner can normally be reached on Monday-Friday 8AM-4:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571)-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

PSH
11/13/06


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